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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/609,296	06/27/2003	Poul Baad Rasmussen	0228us420	5764

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MAXYGEN, INC.
INTELLECTUAL PROPERTY DEPARTMENT
515 GALVESTON DRIVE
REDWOOD CITY, CA 94063

EXAMINER	
SEHARASEYON, JEGATHEESAN	
ART UNIT	**PAPER NUMBER**
1647	

MAIL DATE	DELIVERY MODE
08/21/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/609,296	RASMUSSEN ET AL.	
	Examiner	Art Unit	
	Jegatheesan Seharaseyon, Ph.D	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2007*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *88-104* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *88-104* are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *27 June 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☒ Certified copies of the priority documents have been received in Application No. 09/648, 569.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/31/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. This Office Action is in response to Applicant's election of Group I drawn to claims 88-102 without traverse in the response filed 2/5/2007 is acknowledged. Applicant has cancelled claims 105-121. Although, claims 103-104 are not elected by the Applicant, it is requested that under MPEP § 821.04 claims be rejoined under the rejoinder practice. The Office will rejoin claims 103-104. Therefore claims 88-104 are pending an examined.

Information Disclosure Statement

2. The information disclosure statement filed 7/13/2006 has been fully considered.

Specification

3. Applicant is required to update the priority information by filing an amendment to the first sentence(s) of the specification or an ADS. See MPEP § 201.11.

4. The use of the trademark Betaseron, Avonex and Rebit, etc. have been noted in this application. They should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner, which might adversely affect their validity as trademarks.

5. Throughout the specification IFNβ is indicated as IFNB appropriate correction is required (see for example pages 3, 4 etc.).

Drawings

6. The drawings filed 6/27/2003 are acknowledged. Applicant contends that Figure 2illustrates the antiviral activity of the conjugate (see page 10). However, the Y-axis of the Figure provides no information with respect to what is being measured. Appropriate correction is required.

Double Patenting

7. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., In re Berg, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); In re Goodman, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); In re Longi, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); In re Van Ornum, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); In re Vogel, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and In re Thorington, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

7a. Claims 88-95 and 102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-11 and 14-24 of Pedersen et al. (U.S. Patent No. 6, 531, 122) in view of Rasmussen et al. (U.S. Patent No. 7, 144, 574).

The instant invention is drawn to IFN-β variant, a method of making the variant polypeptide and a method of treatment.

Pedersen et al. (U.S. Patent No. 6, 531, 122) disclose IFN-β variants exhibiting IFN-β activity, comprising a variant sequence, which differs from the wild type human IFN-β sequence SEQ ID NO: 2 in no more than 15 amino acid residues. However, the claims do not specifically recite IFN-β variant of SEQ ID NO: 56 that has the following amino acids changed in SEQ ID NO: 2 (C17S, Q49N, Q51N, D100F, F111N and R113T). The claims also do not recite the molecular weight of PEG.

Rasmussen et al. (U.S. Patent No. 7, 144, 574) disclose changes C17S and D110F of SEQ ID NO: 2 (see claims 17 and 19). In addition, Rasmussen also discloses the molecular weight of the PEG (column17). Therefore, it would have been *prima facie* obvious at the time of the invention to generate PEGylated IFN-β variants with specific amino acid changes because Rasmussen et al. reference discloses the specific amino acid changes and covalently attach a PEG molecule. One of ordinary skill in the art would have been motivated to generate PEGylated proteins because of the stability of the protein. Thus, IFN-β variant of SEQ ID NO: 56 is a obvious embodiment of Pedersen et al. Therefore, the instant invention is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 5-11 and 14-24 of Pedersen et al. (U.S. Patent No. 6, 531, 122) in view of Rasmussen et al. (U.S. Patent No. 7, 144, 574).

7b. Claims 88-95 and 102-104 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-12, 15-21,

23-25 and 27-32 of Pedersen et al. (U.S. Patent No. 7, 238, 344) in view of Rasmussen et al. (U.S. Patent No. 7, 144, 574).

The instant invention is drawn to IFN-β variant, a method of making the variant polypeptide and a method of treatment.

Pedersen et al. (U.S. Patent No. 7, 238, 344) disclose IFN-β variants exhibiting IFN-β activity, comprising a variant sequence, which differs from the wild type human IFN-β sequence SEQ ID NO: 2 in no more than 8 amino acid residues. However, the claims do not specifically recite IFN-β variant of SEQ ID NO: 56 that has the following amino acids changed in SEQ ID NO: 2 (C17S, Q49N, Q51N, D100F, F111N and R113T). The claims also do not recite the molecular weight of PEG.

Rasmussen et al. (U.S. Patent No. 7, 144, 574) disclose changes D110F of SEQ ID NO: 2 (see claims 17 and 19). In addition, Rasmussen also discloses the molecular weight of the PEG (column17). Therefore, it would have been *prima facie* obvious at the time of the invention to generate PEGylated IFN-β variants with specific amino acid changes because Rasmussen et al. reference discloses the specific amino acid changes and covalently attach a PEG molecule. One of ordinary skill in the art would have been motivated to generate PEGylated proteins because of the stability of the protein. Thus, IFN-β variant of SEQ ID NO: 56 is a obvious embodiment of Pedersen et al. Therefore, the instant invention is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-2, 5-12, 15-21, 23-25 and 27-32 of Pedersen et al. (U.S. Patent No. 7, 238, 344) in view of Rasmussen et al. (U.S. Patent No. 7, 144, 574).

7c. Claims 88-95 and 102 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of Rasmussen et al. (U.S. Patent No. 7, 14, 574) in view of Pedersen et al. (U.S. Patent No. 6, 531, 122)..

The instant invention is drawn to IFN-β variant, a method of making the variant polypeptide and a method of treatment.

Rasmussen et al. (U.S. Patent No. 7, 14, 574) disclose IFN-β variants exhibiting IFN-β activity, comprising a variant sequence, which differs from the wild type human IFN-β sequence SEQ ID NO: 2 in no more than 8 amino acid residues. However, the claims do not specifically recite IFN-β variant of SEQ ID NO: 56 that has the following amino acids changed in SEQ ID NO: 2 (C17S, Q49N, Q51N, D100F, F111N and R113T). The claims also do not recite the molecular weight of PEG.

Pedersen et al. (U.S. Patent No. 6, 531, 122) disclose PEGylation (see columns 13-26). Therefore, it would have been *prima facie* obvious at the time of the invention to generate PEGylated IFN-β variants with specific amino acid changes because Pedersen et al. reference discloses covalent attachment of PEG molecules to produce PEGylated interferons. One of ordinary skill in the art would have been motivated to generate PEGylated proteins because of the stability of the protein. Thus, IFN-β variant of SEQ ID NO: 56 is a obvious embodiment of Rasmussen et al. Therefore, the instant invention is rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-19 of Rasmussen et al. (U.S. Patent No. 7, 14, 574) in view of Pedersen et al. (U.S. Patent No. 6, 531, 122).

7d. Claims 96-101are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 85, 87, 93, 96, 97, 99, 100 and 102-108 of copending Application No. 10/351,189. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant invention are also directed to method of producing variant IFN-β with up to 9 amino acid changes to wild-type human IFN-β of SEQ ID NO: 2. Therefore, claims 96-101 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over 85, 87, 93, 96, 97, 99, 100 and 102-108 of copending Application No. 10/351,189.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusions

8. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Bentzien (U. S. Patent No. 6, 514, 729) describes interferon-β muteins. It also describes glycosylation. However, it does not describe the N-glycosylation site(s) contemplated in the instant invention.

9. No claims are allowable.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jegatheesan Seharaseyon, Ph.D whose telephone number is 571-272-0892. The examiner can normally be reached on M-F: 8:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath N. Rao, Ph. D can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Jegatheesan Seharaseyon
Patent Examiner

JSS
Art Unit 1647
August 17th, 2007